

AMENDMENTS TO THE CLAIMS

Claim 1 (original): A vaginal mucoadhesive composition for single dose administration, which is a cream or a gel and comprises sertaconazole or one of its pharmaceutically acceptable salts wherein the proportion of sertaconazole or the salt is higher than 2 % and does not exceed 10 %.

Claim 2 (original): The composition of claim 1, wherein the proportion of sertaconazole or the salt is from 3 to 10%.

Claim 3 (original): The composition of claim 1 or 2, which is a cream.

Claim 4 (currently amended): The composition of ~~any one of claims 1 to 3~~ claim 1, wherein the pharmaceutically acceptable salt is sertaconazole nitrate.

Claim 5 (original): The composition of claim 4, wherein the proportion of sertaconazole nitrate is from 6 to 7%.

Claim 6 (currently amended): The composition of ~~any one of claims 1 to 5~~ claim 1, wherein the cream contains lipophilic excipients, mucoadhesive excipients and one or more preservatives, and the gel dosage form contains mucoadhesive excipients and one or more preservatives.

Claim 7 (original): The composition of claim 6, wherein the lipophilic excipients are selected from glyceryl stearates and their derivatives, ketostearyl alcohols, polyoxyethylene glycol ethers of n-alcohols, liquid paraffin, lecithin oil, glycerol and the like.

Claim 8 (original): The composition of claim 7, wherein the lipophilic excipients are present in a total proportion of from 10 to 40%.

Claim 9 (original): The composition of claim 8, wherein the lipophilic excipients are present in a total proportion of from 30 to 35%.

Claim 10 (original): The composition of claim 6, wherein the mucoadhesive excipients are selected from cellulose polymers, gelatin, colloidal anhydrous silica and polyacrylic acid polymers.

Claim 11 (original): The composition of claim 10, wherein the mucoadhesive excipients are polyacrylic acid polymers.

Claim 12 (original): The composition of claim 11, wherein the polyacrylic acid polymers form a mixture of polyacrylic acid polymer cross-linked with divinyl glycol and acrylic acid polymer cross-linked with sucrose or pentaerythritol allyl esters.

Claim 13 (original): The composition of claim 12, wherein the mixture of polyacrylic acid polymer cross-linked with divinyl glycol and acrylic acid polymer cross-linked with sucrose or pentaerythritol allyl esters are present in a proportion of from 0.1 to 3%.

Claim 14 (original): The composition of claim 13, wherein the mixture of polyacrylic acid polymer cross-linked with divinyl glycol and acrylic acid polymer cross-linked with sucrose or pentaerythritol allyl esters are present in a proportion of from 1 to 1.5%.

Claim 15 (original): The composition of claim 6, wherein the preservatives are selected from parabens, benzoic acid, sorbic acid, boric acid and the like.

Claim 16 (original): The composition of claim 15, wherein the preservatives are present in a total proportion of from 0.01 to 0.3%.

Claim 17 (original): The composition of claim 16, wherein the preservatives are present in a total proportion of from 0.1 to 0.2%.

Claim 18 (currently amended): The composition of ~~any one of the preceding claims~~ claim 1, wherein its content is packed in a single-dose applicator.

Claim 19 (original): The composition of claim 18, wherein its capacity is from 4 to 6 ml.

Claim 20 (original): The composition of claim 19, wherein its capacity is 5 ml.

Claim 21 (currently amended): A kit comprising the composition according to ~~claims 1-20~~ claim 1, and a cream composition for vulvar application containing sertaconazole or one of its pharmaceutically acceptable salts.

Claim 22 (original): The kit of claim 21, wherein the pharmaceutically acceptable salt is sertaconazole nitrate.

Claim 23 (original): The kit of claim 22, wherein sertaconazole nitrate is present in a proportion of from 1 to 3%.

Claim 24 (original): The kit of claim 23, wherein sertaconazole nitrate is present in the proportion of 2%.

Claim 25 (currently amended): Use of the composition according to ~~claims 1 to 20~~  
claim 1 for the manufacture of a pharmaceutically acceptable dosage form for the treatment of vulvovaginal candidiasis of the vagina.

Claim 26 (original): A method for treating vulvovaginal candidiasis, wherein the composition of claim 1 is administered into the vagina of a subject in need of such treatment in a single dose.

Claim 27 (original): The method of claim 26, wherein additionally a composition containing sertaconazole or one of its pharmaceutically acceptable salts is applied to the vulva in single or repeated dose.